UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/560,374	03/29/2007	Kyu Chan Kwon	CMT-0034	9097	
23413 CANTOR COL	7590 03/30/200 BURN, LLP	EXAMINER			
20 Church Stree		DEBERRY, REGINA M			
22nd Floor Hartford, CT 06103			ART UNIT	PAPER NUMBER	
				1647	
			NOTIFICATION DATE	DELIVERY MODE	
			03/30/2009	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

	Application No.	Applicant(s)				
	10/560,374	KWON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Regina M. DeBerry	1647				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply	VIO OET TO EVEIDE A MONTHY	0) OD THUDTY (00) BAYO				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 18 De	ecember 2008.					
	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-5,7 and 9-11</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,5,7 and 9-11</u> is/are rejected.						
7)⊠ Claim(s) <u>4</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment/c)						
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5)  Notice of Informal P 6)  Other:	atent Application				

### Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 18 December 2008, have been entered in full. Claims 6 and 8 are canceled. Claim 1 is amended. Claims 1-5, 7, 9-11 are under examination.

### Withdrawn Objections And/Or Rejections

The rejection to claim 1-11 under 35 U.S.C. 103(a) as being unpatentable over Papadimitriou, US Patent 6,867,182 B2 in view of Yamazaki et al. (reference submitted Applicant; EP 0 909 564 B1) and Cheung et al., WO 00/61169 (reference submitted by Applicant), as set forth at pages 2-5 of the previous Office Action (22 September 2008), is *withdrawn* in view of the amendment and Applicant's arguments that the cited references do not specifically teach the use of 0.1-1.0% w/v of a sugar alcohol and 0.001-0.1% w/v of a polyhydric alcohol (18 December 2008).

### **NEW CLAIM REJECTIONS/OBJECTIONS**

### Claim Rejections - 35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7, 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Vukmirovic et al. (WO 2004/006958 A1).

Application/Control Number: 10/560,374 Page 3

Art Unit: 1647

Vukmirovic et al. teach aqueous pharmaceutical compositions comprising erythropoietin (EPO) (abstract, page 6 and claims). Vukmirovic et al. teach all forms of EPO including recombinant EPO (page 6-7; applies to claim 2). Vukmirovic et al. teach concentrations of EPO is from 1000 IU/ml to 100,000 IU/ml (page 7 and claims; applies to claim 11). Vukmirovic et al. teach buffering agents in the range of 1 mM-50 mM and a pH between 6-8 (page 7 and claims; applies to claim 10). Vukmirovic et al. teach isotonic reagents sodium chloride and calcium chloride and buffering reagents phosphate and citrate buffers. Vukmirovic et al. teach polyhydric alcohols such as glycerol and sugar alcohols such as mannitol and sorbitol and non-ionic surfactants in the range of .005-.5% w/v. Vukmirovic et al. teach neutral amino acids such as glycine at a concentration of 0.5% w/v (page 8 and 11 and claims; applies to claims 1, 3, 5

The Examiner notes that Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

## **Claim Objections**

and 7).

Claim 4 is objected to because it depends from a rejected claim.

#### Conclusion

Claims 1-3, 5, 7, 9-11 are rejected Claim 4 is objected to.

No claims are allowed.

Application/Control Number: 10/560,374 Page 4

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Regina M. DeBerry whose telephone number is (571)

272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts

to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/

Primary Examiner, Art Unit 1647

/R. M. D./

Examiner, Art Unit 1647

3/18/09